

TDMS No. 20201 - 03

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)
WITH AVERAGE SEVERITY GRADES[b]**

Date Report Reqsted: 06/14/2006

Test Type: 26-WEEK

Route: SKIN APPLICATION

Species/Strain: MICE/TG.AC HEMI

TEF TRANSGENICS (PECDF)

CAS Number: 57117-31-4

Time Report Reqsted: 15:27:08

First Dose M/F: NA / 04/21/03

Lab: BAT

C Number: C20201C

Lock Date: 07/24/2004

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

Test Type: 26-WEEK

Time Report Requested: 15:27:08

Route: SKIN APPLICATION

First Dose M/F: NA / 04/21/03

Species/Strain: MICE/TG.AC HEMI

Lab: BAT

| TGAC (FVB/N) HEMIZYGOUS MICE FEMALE | 0 NG/KG | 72 NG/KG | 242 NG/KG | 720 NG/KG | 1520 NG/KG |
|-------------------------------------|----------|----------|-----------|-----------|------------|
| Disposition Summary | | | | | |
| Animals Initially in Study | 20 | 20 | 20 | 20 | 20 |
| Early Deaths | | | | | |
| Moribund Sacrifice | 1 | 4 | 3 | 7 | 6 |
| Natural Death | 2 | 3 | 1 | | 1 |
| Survivors | | | | | |
| Moribund Sacrifice | | | | | 1 |
| Terminal Sacrifice | 17 | 13 | 16 | 13 | 12 |
| Animals Examined Microscopically | 20 | 20 | 20 | 20 | 20 |
| ALIMENTARY SYSTEM | | | | | |
| Liver | (20) | (20) | (20) | (20) | (20) |
| Clear Cell Focus | 1 | | | | |
| Degeneration | | | 1 [2.0] | 1 [1.0] | 2 [2.0] |
| Fatty Change | 1 [1.0] | 2 [1.0] | 1 [1.0] | 11 [1.0] | 3 [1.0] |
| Hematopoietic Cell Proliferation | 1 [1.0] | 1 [1.0] | 4 [1.0] | 10 [1.4] | 15 [1.9] |
| Hepatodiaphragmatic Nodule | 1 | | | | |
| Inflammation | 19 [1.2] | 18 [1.2] | 20 [1.2] | 18 [1.4] | 13 [1.4] |
| Myelodysplasia | | | | | 1 [3.0] |
| Necrosis | 7 [1.6] | 5 [1.0] | 7 [1.3] | 8 [1.3] | 6 [1.7] |
| Pigmentation | 10 [1.0] | 8 [1.0] | 13 [1.1] | 11 [1.0] | 10 [1.2] |
| Vein, Thrombosis | | | 1 [2.0] | | |
| Mesentery | (1) | (1) | (0) | (0) | (0) |
| Fat, Necrosis | 1 [3.0] | 1 [3.0] | | | |
| Pancreas | (0) | (1) | (0) | (0) | (0) |
| Cyst | | 1 [2.0] | | | |
| Salivary Glands | (1) | (0) | (0) | (0) | (0) |
| Stomach, Forestomach | (6) | (2) | (2) | (5) | (8) |
| Stomach, Glandular | (1) | (0) | (0) | (0) | (0) |
| Glands, Hyperplasia | 1 [2.0] | | | | |
| Tooth | (6) | (6) | (3) | (1) | (2) |
| Malformation | | | | 1 | |

CARDIOVASCULAR SYSTEM

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Control data contained within this report was collected on study 20201-01

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Lab: BAT

| TGAC (FVB/N) HEMIZYGOUS MICE FEMALE | 0 NG/KG | 72 NG/KG | 242 NG/KG | 720 NG/KG | 1520 NG/KG |
|-------------------------------------------------------------------------------------------|-----------------|-----------------|------------------|--------------------------------------|-----------------------------|
| Heart Thrombosis | (0) | (0) | (0) | (0) | (1) 1 [3.0] |
| ENDOCRINE SYSTEM | | | | | |
| Pituitary Gland Cyst | (0) | (0) | (1) 1 [3.0] | (1) | (0) |
| GENERAL BODY SYSTEM | | | | | |
| None | | | | | |
| GENITAL SYSTEM | | | | | |
| None | | | | | |
| HEMATOPOIETIC SYSTEM | | | | | |
| Lymph Node Hyperplasia, Lymphoid Hyperplasia, Plasma Cell Inflammation | (0) | (0) | (0) | (8) 4 [2.8] 1 [3.0] 2 [2.0] | (4) |
| Lymph Node, Mandibular Hyperplasia, Lymphoid Hyperplasia, Oncocytic Inflammation | (0) | (1) 1 [3.0] | (0) | (3) 1 [2.0] 1 [1.0] | (3) 2 [2.0] |
| Lymph Node, Mesenteric Hyperplasia, Lymphoid | (1) | (1) 1 [2.0] | (0) | (2) 2 [2.5] | (1) |
| Spleen Hematopoietic Cell Proliferation Myelodysplasia | (20) 3 [1.3] | (20) 7 [1.4] | (20) 13 [1.8] | (20) 14 [2.3] | (20) 14 [2.2] 1 [4.0] |
| Thymus Atrophy | (20) 3 [2.7] | (19) 3 [2.3] | (19) 6 [2.3] | (19) 6 [2.3] | (18) 12 [3.1] |
| INTEGUMENTARY SYSTEM | | | | | |
| Skin Cyst Epithelial Inclusion | (4) | (4) | (8) 1 | (7) | (13) |

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Lab: BAT

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|---------------------------------------------|---------|----------|-----------|-----------|------------|
| Fibrosis | 1 [2.0] | | 1 [3.0] | 1 [2.0] | |
| Hyperplasia, Mast Cell | | | | | 1 [3.0] |
| Hyperplasia, Squamous | 4 [1.8] | 1 [2.0] | 4 [2.3] | 3 [2.7] | 3 [1.7] |
| Inflammation, Chronic Active | 3 [1.3] | 1 [1.0] | 3 [1.3] | 6 [1.8] | 10 [1.6] |
| Ulcer | 1 [1.0] | | | | |
| Skin, Control Dermis | (20) | (20) | (20) | (20) | (20) |
| Inflammation, Chronic Active | | | 1 [1.0] | 5 [1.0] | 1 [1.0] |
| Skin, Control Epidermis | (20) | (20) | (20) | (20) | (20) |
| Hyperplasia, Squamous | | | | 1 [1.0] | |
| Skin, Site Of Application | (20) | (20) | (20) | (20) | (20) |
| Fibrosis | 1 [2.0] | | | | |
| Hyperplasia, Mast Cell | | | 1 [2.0] | | 1 [2.0] |
| Hyperplasia, Squamous | 1 [3.0] | 8 [2.0] | 10 [2.4] | 18 [2.3] | 16 [2.3] |
| Inflammation, Chronic Active | 2 [1.0] | 14 [1.6] | 18 [1.9] | 20 [2.1] | 20 [2.2] |
| Skin, Soa No Mass | (20) | (20) | (17) | (13) | (12) |
| Hyperplasia, Mast Cell | | 1 [2.0] | | | |
| Hyperplasia, Squamous | 1 [1.0] | 6 [1.2] | 8 [1.1] | 9 [1.1] | 6 [1.2] |
| Inflammation, Chronic Active | 3 [1.0] | 6 [1.2] | 11 [1.2] | 12 [1.3] | 9 [1.6] |
| Ulcer | | | | 1 [1.0] | |
| MUSCULOSKELETAL SYSTEM | | | | | |
| None | | | | | |
| NERVOUS SYSTEM | | | | | |
| None | | | | | |
| RESPIRATORY SYSTEM | | | | | |
| Lung | (20) | (20) | (20) | (20) | (20) |
| Alveolar Epithelium, Hyperplasia | | | | 1 [3.0] | 1 [2.0] |
| Alveolus, Infiltration Cellular, Histiocyte | | 1 [1.0] | 1 [1.0] | 3 [1.0] | 1 [1.0] |
| Interstitialium, Inflammation | 1 [1.0] | 1 [1.0] | 1 [1.0] | | 5 [1.2] |
| Perivascular, Inflammation | 2 [1.0] | | | 2 [1.0] | 1 [1.0] |
| Serosa, Inflammation, Chronic Active | 7 [1.0] | | 1 [1.0] | 7 [1.0] | 2 [1.0] |

SPECIAL SENSES SYSTEM

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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|-------------------------------------|---------|----------|-----------|-----------|------------|
| None | | | | | |
| URINARY SYSTEM | | | | | |
| Kidney | (0) | (0) | (0) | (0) | (1) |

*** END OF REPORT ***